MAXIMUM STRENGTH GAS RELIEF- simethicone capsule, gelatin coated Spirit Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Maximum Strength Gas Relief

Active ingredient (in each softgel)

Simethicone 250 mg

Purpose

Anti-gas

Use

relieves bloating, pressure or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists

Keep out of reach of children.

Directions

- swallow one or two softgels after a meal
- do not exceed two softgels per 24 hours except under the advice and supervision of a physician

Other information

• store at room temperature 59°-86°F (15°-30°C)

Inactive ingredients

D&C Red #33, FD&C Blue #1, gelatin, glycerin, povidone, purified water, sorbitol sorbitan, titanium dioxide

Questions or Comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

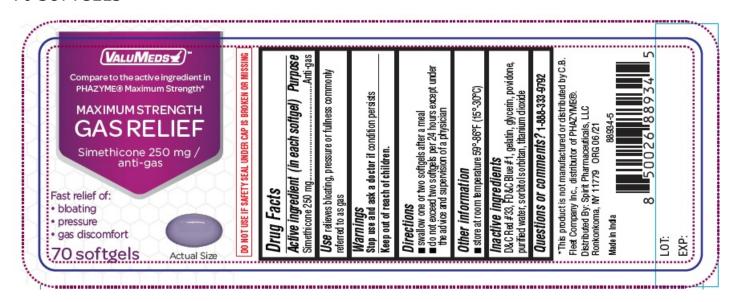
VALUMEDS MAXIMUM STRENGTH GAS RELIEF

SIMETHICONE 250 mg/ Anti-gas

Compare to the active ingredient in PHAZYME® Maximum Strength*

*This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of PHAZYME®.

70 SOFTGELS



MAXIMUM STRENGTH GAS RELIEF

simethicone capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4165
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	250 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POVIDONE (UNII: FZ989GH94E)		
SORBITOL SOLUTION (UNII: 8KW3E207O2)		

WATER (U	NII: 0590	(FOKOOR)
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Product Characteristics			
Color	purple	Score	no score
Shape	CAPSULE (oval)	Size	12mm
Flavor		Imprint Code	250
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:68210- 4165-7	70 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	06/23/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 11/2021 Spirit Pharmaceuticals LLC